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FINAL TRANSCRIPT

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Event Transcript

BPUR - Biopure Corporation Conference Call To Discuss the Regulatory Status of Hemopure

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BPUR - Biopure Corporation Conference Call To Discuss the Regulatory Status of Hemopure

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Kate Winkler

PRESENTATION

Operator

Good afternoon. My name is Melissa and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Biopure Special Announcement Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer period. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press star then the number two on your telephone keypad. Thank you. I will now turn the conference over to Douglas Sayles, Director of Corporate Communications. Mr. Sayles, you may begin your conference.

Douglas Sayles

Good afternoon, everyone, and thank you for joining us on short notice. Before we talk about the progress that we're making in the FDA regulatory process, I need to point out that during the call we'll make projections and other forward-looking statements which involve risks and uncertainties that can cause the company's actual results or performance to differ materially from those projected. The condensed list of these respective factors appears at the end of today's press release which you can access on our website on the Internet at Biopure.com or you can reference these risk factors in our SEC filings on our website. Right now I'd like to turn the call over to Tom Moore, who is going to discuss today's news. Thank you.

Thomas A. Moore - *Biopure - CEO and President*

Good afternoon, everybody. I'm joined this afternoon, in addition to Doug, by Howard P. Richman, our SVP of Regulatory Affairs and Operations, and Ronald Richards, our CFO and SVP of Business Development. As most of you probably know, less than two hours ago, we received written notification from the Food and Drug Administration of their intention to complete the review of our biologic license application for Hemopure by August 29th. This notification is consistent with PDUFA guidelines which provide that the agency will attempt to get a response to us of some kind to our application filed on July 31, 2002 by June 1st . The same PDUFA regulations allow for a one-time 90-day extension based on the agency's judgment of what's appropriate in the review of our application.

We view this notification as a very position development for Hemopure. First of all, we have a date which the agency has indicated their intent to give us an action letter. Second, it confirms what we already knew, that is, that the agency has

devoted considerable effort to this application. And third, as we also already knew, that now our investor community knows, there is nothing in our application which is warranted a denial of that application at the three key decisions points we've passed so far in the PDUFA process. By that, I mean our BLA was accepted, it was also continued through the mid-cycle review conducted by the agency, and now, at the PDUFA guideline date for a first response, we've not had a denial, but rather a going forward to additional consideration. The added time we're going to get over the next three months will not only allow us to insure we can fully answer any additional questions the FDA might choose to send our way, but also allow us to complete legal negotiations and to continue forward with the commercial preparations we are making against a hopeful approval on August 29th for the name of introducing this product on or about the October introductory guideline we mentioned in our conference call last week.

So we feel very positive about this, but quite understandably, we want to be in touch with our investor public and give them an opportunity to answer questions as well, ask questions as well, so we're going to answer them. And to help me do that, I'm going to turn to Howard Richman to answer many of these questions. As some of you can tell, I'm suffering from a severe cold coming from the non-existent strain we have in Boston this year. And so we'll be sharing question and answering duties with Howard this afternoon. Those are our comments. We'll now be happy to answer any questions.

Operator

At this time, I would like to remind everyone, in order to ask a question, please press star then the number one on your telephone keypad. We'll pause for a moment to compile the Q&A roster. Your first question comes from Sapna Srivastava with ThinkEquity Partners.

QUESTIONS AND ANSWERS

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Hi, guys. Congratulations on the new progress. A quick question - - did the FDA request any additional data to be submitted, or why do you think that basically the FDA extended the timeline for the review process?

Thomas A. Moore - *Biopure - CEO and President*

The FDA did not request any additional data and I'll let Howard comment on the extension of the review process.

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

Hi, Sapna, this is Howard. This is what normally happens with any submission. As Tom has told the public over the past many months, is that we are in continued dialogue with the agency and during that period of time, they have requested information which we have sent back to them. It's a normal process with any application. Be that as it may, the agency, during the course of reviewing the information has the opportunity to take additional time to allow them to give a complete and additional thorough review of all information to make a thorough conclusion on application. This type of response from the FDA is very common with biologic licensing applications. Most recently, in 2001 and 2002, of the 11 BLAs that were submitted to the Food and Drug Administration, all 11 of them went on to the extended period of time for review which was outside the normal PDUFA 10 months. It is within the PDUFA guidelines to allow them to do that and they still meet their matrix for approval for their guidance acumen.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Can you give us any indication as to which data subset the FDA is looking at? Is it clinical, manufacturing or is it just a combination of the whole thing?

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

It's really clinical data as far as we know. As we've shared previously with the public, we believe that the CMC portion of the BLA has basically been covered. Now we could get a question tomorrow which would make that statement no longer accurate but based on everything we've seen the CMC work is completed.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Okay, thank you.

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

Thank you, Sapna.

Operator

Our next question comes from Kirk Lang with Gwitt Broadway Partners.

Kirk Lang - *Gwitt Broadway Partners - Analyst*

Hey, Tom, great news.

Thomas A. Moore - *Biopure - CEO and President*

Thank you, Kirk.

Kirk Lang - *Gwitt Broadway Partners - Analyst*

In your Q2 release that we just talked about, you indicated that Biopure believes it has sufficient cash to fund operations through November of 2003. Was that cash on hand or was that all for you having to utilize as standby equity agreements with the megastore capital markets?

Thomas A. Moore - *Biopure - CEO and President*

It's cash on hand.

Kirk Lang - *Gwitt Broadway Partners - Analyst*

Very good, thank you.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

Our next question comes from Richard Adams with Bennett Lawrence.

Richard Adams - *Bennett Lawrence - Analyst*

Hi, thanks. I guess I'm a little bit confused on the timing of the submission of whatever it is you did submit to the FDA given that your original BLA was submitted in July 31st of last year. I guess my question is why are you still having to provide information to the FDA? You said mid-May there was a resubmission of some sort. Why nine and a half months after the original BLA was submitted are you still having to provide information?

Thomas A. Moore - *Biopure - CEO and President*

It's actually, Richard, it's a continual process of providing information. I'm going to let Howard comment on this specifically, but it would be difficult to categorize how many hundreds of questions we've answered in the review of this BLA to date. This mid-May submission was some additional analysis which we provided on data that was already in the BLA. At the time, we didn't consider it a major amendment to the BLA but the FDA looked at that as a reason to extend it. But I'll let Howard comment on that.

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

Good afternoon, Sir. How are you? Just as a point of clarification, this is a normal occurrence. I've been lucky to be involved with 12 other approval processes outside of Biopure and this is a normal thing that happens. We're, in fact, in constant contact with the agency when they're requesting information in real time. So this is not anything new that can happen. And what we have done is supply responses back to their continual questions to allow them, again, as I mentioned earlier, to give complete and thorough response to this first in class application.

Richard Adams - *Bennett Lawrence - Analyst*

I understand there was a continuing dialogue and questions and answers, but it would seem that for there to be some sort of submission that would extend the PDUFA date another two months, it would have to be something material. And I guess I'm just surprised that nothing was disclosed in mid-May when this additional submission was made.

Thomas A. Moore - *Biopure - CEO and President*

To be clear, we were simply responding to a new set of questions from FDA. It did not involve any new data. And so frankly, it was well within the range of other questions we've answered in the past. When we made that response, we didn't characterize it as a major amendment to the BLA. I think the FDA chose to do that and I think that really, how do I phrase this diplomatically, I think that's a way for them to get this additional consideration time as opposed to some startling new insight on the application. But that's not my role to call. I would say, as Howard has already said, so far the FDA's extended on 11 straight BLAs, so we're number 12.

Richard Adams - *Bennett Lawrence - Analyst*

Was there any discussion about whether you'll need an FDA panel?

Thomas A. Moore - *Biopure - CEO and President*

No. All I'd say is, by the agency's making their intention to give an answer by August 29th, that rules out a panel given that the next panel scheduled, I believe, is in September. I think the decision the FDA made not to use a panel appears to still hold.

Richard Adams - *Bennett Lawrence - Analyst*

Okay, thank you.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

Your next question comes from Gabe Hoffman with Occipital Capital Management.

Gabe Hoffman - *Occipital Capital - Analyst*

Good afternoon, gentlemen. Thank you for hosting the call. I was just curious - - one comment that you just made that FDA has extended on 11 straight BLAs. Whose BLAs? I'm not sure. Can you tell me exactly what you're referring to there?

Thomas A. Moore - *Biopure - CEO and President*

We're referring to standard BLAs. That is, those that are not submitted for accelerated approval but are normal standard timing and we're referring to 11 BLAs submitted in 2001 and 2002. And those were 11 different biologic products.

Gabe Hoffman - *Occipital Capital - Analyst*

So the last 11 BLAs to be reviewed, the FDA has extended on all of them?

Thomas A. Moore - *Biopure - CEO and President*

That is correct. Standard BLAs.

Gabe Hoffman - *Occipital Capital - Analyst*

Oh, I wasn't -- standard BLAs, okay, I wasn't aware of that. Could you please be a little more specific in terms of - - the company has submitted additional analyses of previously submitted data. Could you be a little more specific as to what elements of the clinical data that that refers to?

Thomas A. Moore - *Biopure - CEO and President*

I can't be a lot more specific.

Gabe Hoffman - *Occipital Capital - Analyst*

I mean, is it safety, is it statistical procedure, is it some auditing of patient records? I mean, could you just be somewhat more specific?

Thomas A. Moore - *Biopure - CEO and President*

Well, all patient records have been audited and so all that's been done, so that's not at issue as far as I know anyway.

Gabe Hoffman - *Occipital Capital - Analyst*

Or merely is it formatting or you know?

Thomas A. Moore - *Biopure - CEO and President*

It's actually - - it was a dialogue really about how to look at the clinical data. As you know, there are various analyses used to

look at our efficacy and safety data and we just had a dialogue about the different ways you could look at the analyses that are performed on the data. And that's really as far as I want to characterize it.

Gabe Hoffman - *Occipital Capital - Analyst*

But could you just give us maybe a broader ballpark sense as to - - you know, just a broad area that it is - - is there a specific area that it's in that's a broad area that maybe you could characterize it? That's more specific than just it's the clinical data?

Thomas A. Moore - *Biopure - CEO and President*

Well, I mean, all the clinical data has to do with safety and efficacy. That's the only thing in measure in these clinicals. And so, the dialogue is over those clinical and safety and efficacy data. And again, we have answered some questions on a pretty broad basis. When I talk about it as how to look at the clinical analysis, it's exactly what it was. So I think that's as far and as specific as I really want to be at this point.

Gabe Hoffman - *Occipital Capital - Analyst*

Okay. Thank you very much.

Operator

Your next question comes from Stan Setlock with Silver Syndicate.

Stan Setlock - *Silver Syndicate - Analyst*

Yes. Assuming that you get the normal approval that's expected, what quarter would you be looking to make a profit in?

Thomas A. Moore - *Biopure - CEO and President*

Well, what we have shared with the investing public in the past has been that with the capacity we have on hand in our Cambridge, Massachusetts facility, which currently is in the ballpark of 70,000 to 75,000 units per year, while we can upgrade that to the 90,000 to 100,000 units a year, even at that capacity, we don't believe we will be able to register a total company profit where the revenue from these sales offsets all the fixed costs and research costs that we have planned, we don't think we'll be able to reach that profit until we can upgrade our capacity further with the new installation we intend to open in 2006.

Stan Setlock - *Silver Syndicate - Analyst*

Thank you very much.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

Your next question comes from Kate Winkler with Shoreline Pacific.

Kate Winkler

Oh, hi, sorry. Not necessarily slow line, but shoreline. Hi guys. I just wanted to ask the next logical question about the previous 11 BLAs and what proportion of those were approved?

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

The - - at this point, and remember, some of this is pretty recent stuff, like 2002, which means they were submitted in 2002, of those 11, 4 have been approved, none have been rejected. Some are still in dialogue. Some are doing additional clinical research.

Kate Winkler

But has the response time passed for all of those in the sense that this 90 day, or are we amidst 90 days for some of those?

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

I believe all of those have reached the full 13 months, if you will, of standard review period.

Kate Winkler. Okay. And so what that means now in terms of future options based on previous precedent for you guys is outright approval obviously still. But we've still got some of this similar potential outcomes being extending the trials or extending the review further, right?

Thomas A. Moore - *Biopure - CEO and President*

That's certainly possible. It's, I think, it's our belief that we will get a full action letter which will be more definitive than that. But that's our belief, it's not a commitment made.

Kate Winkler

Is there any reason why you believe that in light of the fact that only four have actually had that happen?

Thomas A. Moore - *Biopure - CEO and President*

Well, that's what be believe, so I guess we have - - we don't base that belief on nothing.

Kate Winkler

All right, well thanks.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome, Kate.

Operator

Your next question comes from Dexter Bland, private investor. Dexter, your line is open.

Dexter Bland - *private investor*

Thomas, I was reading your statement that you submitted that you were pleased with the FDA's progress and I would have put that I was disappointed because it should have been approved. I mean, either it works or it don't work and three months ain't gonna change anything. So I've been invested a long time and I was just very disappointed and I'm sure you fellas are too. .I just wanted to make that comment.

Thomas A. Moore - *Biopure - CEO and President*

I understand. You're absolutely right to say I would have preferred outright approval and perhaps an investment in our stock. Just kidding about that, FDA. But I guess as we look at the total picture, we feel like we're continuing to make progress on this.

Dexter Bland - *private investor*

Thanks a lot.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

You have a follow-up question from Richard Adams with Bennett Lawrence.

Richard Adams - *Bennett Lawrence - Analyst*

Hi, sorry. Just one more quick one. Are you now confident that you've given the FDA all of the information it needs to make a decision?

Thomas A. Moore - *Biopure - CEO and President*

I guess it depends on whether the FDA should choose to ask us any further questions. And so, I feel confident that all the data required to make a decision is there. We may yet have some more dialogue about that data, but we do think we have a full and complete application.

Richard Adams - *Bennett Lawrence - Analyst*

One last thing. On the last conference call, you all mentioned three new insurers in South Africa that were covering Chemopure. I haven't seen that disclosure on the website. I think you guys said that you had posted that.

Thomas A. Moore - *Biopure - CEO and President*

Very shortly. I'm sorry for the delay on that, but there will be no problem getting all three up there.

Richard Adams - *Bennett Lawrence - Analyst*

Can you tell us - -

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

We're just back checking a couple of those things and it will be up next week.

Richard Adams - *Bennett Lawrence - Analyst*

Okay, thank you.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

Again, if you would like to ask a question, please press star then the number one on your telephone keypad. You do have a follow up question from Gabe Hoffman with Occipital Capital Management.

Gabe Hoffman - *Occipital Capital - Analyst*

Thank you, gentlemen. Actually, that was the question that you may recall that I had asked on the previous conference call is who the three South African insurance companies are. Just to expand on the previous question about that, what is it exactly that needs to be back checked? I mean, the company said that there are three insurers. That was said a week and a half ago. Why - - I mean, it's the only market in which the product is approved. One would think that you would have that at your fingertips or within a near immediate period of time.

Thomas A. Moore - *Biopure - CEO and President*

Everything you say is perfectly reasonable. I frankly was not aware that it was not yet on the site and we'll have it on the site absolutely ASAP.

Gabe Hoffman - *Occipital Capital - Analyst*

Okay. Could you define ASAP?

Thomas A. Moore - *Biopure - CEO and President*

Gosh, here it is - - we'll have it on Monday.

Gabe Hoffman - *Occipital Capital - Analyst*

Okay, great. Thank you very much.

Operator

Your next question comes from Roberto McNuln with Bridger Capital.

Roberto McNuln - *Bridger Capital - Analyst*

Is there any possibility that there could be an additional extension past the August 29th?

Thomas A. Moore - *Biopure - CEO and President*

Fundamentally, no. Under PDUFA guidelines, the FDA is allowed one 90 day extension. But beyond that, I mean, it is possible but at that point they break away from PDUFA guidelines and the agency these days is not supposed to do that.

Roberto McNuln - *Bridger Capital - Analyst*

Given the fact that there's a September 19th tentative B-Pak committee meeting, I just was interested in knowing whether that could be a possibility with say a one month extension to be included on that panel?

Thomas A. Moore - *Biopure - CEO and President*

We don't think so. Based on the agency's reaffirmation of the August 29th date, we think obviously what they're saying is that's not in our plan.

Roberto McNuln - *Bridger Capital - Analyst*

To get some more information about the additional data asked for - - given your assessment that the questions asked were very broad, I'm still unclear as to why then at this late in the date it would require a three month delay. I would understand if the questions were very detailed that the FDA would ask for - - would take that additional time. But your assessment of the questions being very broad makes me want to get some more detail about that.

Thomas A. Moore - *Biopure - CEO and President*

I think - - well, I guess the question is, the FDA chose to look at this as a major amendment to the BLA. That's sort of a decision they make which allows them those three months of extra time. I don't know whether or not - - and it's also standard procedure that they - - if we submit new information about any aspect of the product or new analysis about any aspect of the product, whether it's pivotal to their decision or not, they can decide that that's a reason to go for the extension. So I'm not sure whether or not the data we submitted, we did not submit any new data, whether that was a reason for the extension of whether the echo simply needed an extension, period.

Roberto McNuln - *Bridger Capital - Analyst*

When did the FDA make that request for the information that resulted in the extension?

Thomas A. Moore - *Biopure - CEO and President*

Well, again, you're making the connection that the information was the reason for the extension. I'm not sure whether that's the case. But the request for that information was about May 1st.

Roberto McNuln - *Bridger Capital - Analyst*

About May 1st. Okay, thank you.

Operator

Your next question comes from Michael Wood with Fonstock Oppenheimer.

Michael Wood - *Fonstock Oppenheimer - Analyst*

Gentlemen, good job. This is Michael Wood. How are you?

Thomas A. Moore - *Biopure - CEO and President*

Thank you, Michael. We are well and we hope you're well.

Michael Wood - *Fonstock Oppenheimer - Analyst*

Well, I am, and I've just got to know your company over the last 6 or 8 months or so and I've been talking to people inside and outside. My question is this - - out of the people that are in the room on your side that are listening, how many people expected them to pull the extension for three more months? Is there anyone on the management team that thought that might happen?

Thomas A. Moore - *Biopure - CEO and President*

I think, first off, I haven't polled the room, so we may go around right now and do it. I think Mr. Sayles, who is always a pessimist, probably would have bet on the extension. I think it's fair to say we knew that was a possibility. The FDA, as we shared, the FDA sort of indicated to us that they were aiming to give us a full and complete review within the PDUFA guidelines, but at no point does that obligate them. Howard, do you want to give me your point of view?

Howard P. Richman - *Biopure - SVP Regulatory Affairs and Operations*

Yeah. It's not surprising, basically, because the information had been colleted over the past year since the submission and something of an understandable lull. This is the first electronic BLA Sever has ever received and quite high in volume and the data is in many places to review and it does take a lot of work to get it done. Because our most recent submission to them from the beginning of May, as Tom mentioned, it provided them with some new analyses that they had requested to help in their review cycle.

Michael Wood - *Fonstock Oppenheimer - Analyst*

Okay. It seems to me that if they wanted to reject the product at this point in time, it would have been easy for them to have just done it toady or Monday. Is that true?

Thomas A. Moore - *Biopure - CEO and President*

Yes.

Michael Wood - *Fonstock Oppenheimer - Analyst*

Okay. Well, thank you very much. I look forward to seeing the product progress over the next three months. Good luck.

Thomas A. Moore - *Biopure - CEO and President*

Thank you, Michael.

Michael Wood - *Fonstock Oppenheimer - Analyst*

Thank you.

Operator

Your next question comes from Tag Vichu with Moores Tabot.

Tag Vichu - *Moores Tabot - Analyst*

Good afternoon, everybody there. I have been traveling the same road you have for about 4 years, watching your company as it's progressed. I'm particularly interested in simply one aspect of the FDA's review period going now to August 29th. Is it conceivable or possible that the FDA could complete the review in a shorter period of time than August 29th?

Thomas A. Moore - *Biopure - CEO and President*

No, Sir. Because under the guidelines, when they are granting a extension which we agreed to, it has to be the full 90 days.

Tag Vichu - *Moores Tabot - Analyst*

I see. Does this delay affect the progress that's going on in South Carolina?

Thomas A. Moore - *Biopure - CEO and President*

Because we haven't completed the negotiation on the financing, it's hard to say for sure. And point of fact is we've been trying to be very prompt in getting out to the public with this information. They haven 't checked in with the financial folks to see whether or not that changes their perspective. On the whole, our partners, the Sumter Realty Group, are the folks who actually do the money raising, so we don't talk directly to the financiers. Rather, we talk to them who in turn do that negotiation. Because these negotiations are all conducted in the context of, if you will, we approach where if we - - which was going to get us financing regardless of the date of approval, I don't think it's going to make a whole lot of difference. But we'll have to talk to our pals at the Sumter Realty Group to see what the latest is and where they stand.

Tag Vichu - *Moores Tabot - Analyst*

Sure. I realize it's somewhat of an unfair question given the timeliness of the announcement. The - - I had another question. I'm not sure I can remember what it was. Well, I'll have to call Doug at some other time. Thanks very much and good luck with the next 90 days.

Thomas A. Moore - *Biopure - CEO and President*

Thank you very much.

Operator

Your next question comes from Todd Sidwell, private investor.

Todd Sidwell - *private investor*

Hello.

Thomas A. Moore - *Biopure - CEO and President*

Good afternoon, Todd.

Todd Sidwell - *private investor*

My question is about the new facility you mentioned opening in 2006. If I understand from the last question, that is going ahead or has always been planned for, regardless of what the FDA does at this point?

Thomas A. Moore - *Biopure - CEO and President*

Yes.

Todd Sidwell - *private investor*

And how will that increase some options for you?

Thomas A. Moore - *Biopure - CEO and President*

That will provide us with an incremental 500,000 units per year of production. In other words, take our capacity from just under 100,00 to just under 600,000 units per year. It also will generate a significant improvement in the cost of making the products

which will contribute almost as much to the profitability as the additional volume.

Todd Sidwell - *private investor*

And you feel this will put the company then well on the road to profitability I assume?

Thomas A. Moore - *Biopure - CEO and President*

Yes. With that facility, we'll have all we need to begin to give our shareholders a long-awaited and much deserved good return on their investment.

Todd Sidwell - *private investor*

Great. Thank you very much. Good luck.

Operator

Your next question comes from Steve Happas, Dakota Investments.

Steve Happas - *Dakota Investments - Analyst*

Good afternoon, guys.

Thomas A. Moore - *Biopure - CEO and President*

Good afternoon, Steve.

Steve Happas. A couple of things as I'm relatively new to Biopure over the last 3 to 6 months. Have you before given - - upon FDA approval, crossing the fingers of you guys, looks like you're going to get it, but after you do get it - - have you guys discussed publicly of any type what it's going to mean revenue torque for the company going forward here in the first 12 months and then out?

Thomas A. Moore - *Biopure - CEO and President*

We've not provided any revenue guidance.

Steve Happas - *Dakota Investments - Analyst*

Would it be safe to say that, and as mentioned before on the previous conference call that you did not get denied, but said maybe around the $800 per unit that would be in the ballpark of what each unit would cost? I mean would sell for?

Thomas A. Moore - *Biopure - CEO and President*

I stand by what I said then. It's in the ballpark.

Steve Happas - *Dakota Investments - Analyst*

So can I make the assumption that to produce anywhere between 75,000 and 100,000 units, let's say from a top standpoint, that it could mean about $80 million in top line the first 12 months that you ship the product?

Thomas A. Moore - *Biopure - CEO and President*

I can't argue with your math, but I would also say that it would probably be unlikely that we would be able to ship full capacity from the first day it's available as there is a considerable marketing and selling job that needs to be done with physicians with any new product, particularly one like this which is totally first in class.

Steve Happas - *Dakota Investments - Analyst*

Right. And would that target still be October 1st even though the August 29th now decision will be made?

Thomas A. Moore - *Biopure - CEO and President*

Our objective is going to be to use this time well so that we experience minimum delay in launching commercially. So yes, our target still will be to be in business in October.

Steve Happas - *Dakota Investments - Analyst*

October 1st, and then would you say maybe 25 to 50% then, of those 75,000 units at least would be able to be shipped in the first 6 to 12 months?

Thomas A. Moore - *Biopure - CEO and President*

Steve, now you're trying to trap me into giving guidance.

Steve Happas - *Dakota Investments - Analyst*

Well, I'm just trying to get - -

Thomas A. Moore - *Biopure - CEO and President*

It's like a sharp object and you should never carry them unless it's pointing at me. So I can't reaffirm that for you today at least.

Steve Happas - *Dakota Investments - Analyst*

Okay. I appreciate it and great job, guys, and I hope all goes well.

Thomas A. Moore - *Biopure - CEO and President*

Thank you, Steve.

Operator

Your next question comes from Ronald Risotto with West Rock Investors.

Ronald Risotto - *West Rock Investors - Analyst*

Good afternoon, gentlemen. How are you?

Thomas A. Moore - *Biopure - CEO and President*

Hi, Ronald.

Ronald Risotto - *West Rock Investors - Analyst*

I guess my question is going to be pertaining to Oxyglobin and do you have plans to more aggressively go after the veterinary market?

Thomas A. Moore - *Biopure - CEO and President*

Absolutely. In the month of, in the last month, we have introduced the new peer to peer marketing program which has already engaged 175 veterinarians in conference call discussions about the product where there is considerable peer to peer selling. Further, we have filed with the FDA the necessary material to allow us to launch a new 60 ml bag format this summer which is roughly half the size of the current bag which will make it much more economical as well as easier to use this product on smaller dogs and the like. So you will find, as a hallmark of what we try to do over the next few months, will be to drive the Oxyglobin business and preliminarily at least, we're encouraged by what we're seeing. Orders have held up very well after the huge volume we shipped after we took the product off shipment hold.

Ronald Risotto - *West Rock Investors - Analyst*

Terrific. Great job, guys. Thank you so much.

Thomas A. Moore - *Biopure - CEO and President*

Thank you, Ronald.

Operator

Your next question comes from Ken Martin Halpine with Emerald Asset Management.

Ken Martin Halpine - *Emerald Asset Management - Analyst*

Good afternoon and congratulations. When do you expect to release your next earnings for this quarter?

Thomas A. Moore - *Biopure - CEO and President*

Well, having just done a quarterly, it will be roughly in three months minus one week. Let me see - -

Doug Sayles - *Biopure - Director of Corporate Communications*

I believe it's August 22nd or whatever that Thursday is, our quarter close is at the end of July.

Ken Martin Halpine - *Emerald Asset Management - Analyst*

Very good. Thank you.

Thomas A. Moore - *Biopure - CEO and President*

You're welcome.

Operator

At this time there are no further questions.

Thomas A. Moore - *Biopure - CEO and President*

I'd like to thank everybody for getting together with us here at short notice. We feel very positive about this latest announcement and rest assured we'll be working very hard over the next 3 months to answer any other questions the FDA has and also to make ready for what we hope for will be a very successful introduction.

Operator

Thank you for participating in today's conference. You may now disconnect.
